DEPARTMENT OF **HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-144/S-018

FEB 3 1999

Novartis Pharmaceuticals Company
Drug Regulatory Affairs
Attention: Ms. Donna M. Vivelo
59 Route 10
East Hanover, NJ 07936-1080

Dear Ms. Vivelo:

Please refer to your supplemental new drug application dated November 20, 1998, received November 25, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Transderm-Nitro (nitroglycerin) Transdermal System.

This supplemental new drug application provides for final printed labeling revised to add the following text to the CONTRAINDICATIONS section:

> Use of Transderm-Nitro (nitroglycerin) Transdermal system is contraindicated in patients using Viagra (sildenafil) because sildenafil may amplify the vasodilatory effects of Transderm-Nitro resulting in severe hypotension.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the final printed labeling included in your November 20, 1998 submission. Accordingly, the supplemental application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 2 1 CFR 3 14.80 and 314.81.

At your next printing, we ask that you add the following bolded statement as the first warning under **WARNINGS:**

> **Amplification of the vasodilatory effects of Transderm-Nitro by sildenafil can result in severe hypotension. The time course and dose dependence of this interaction have not been studied. Appropriate supportive care has not been studied, but it seems reasonable to treat this as a nitrate overdose, with elevation of the extremities and with central volume expansion.**

If you have any questions, please contact:

Mr. Gary Buehler
Regulatory Health Project Manager
(301) 594-5332

Sincerely yours,

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research